MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNEIL CONSUMER P
FORT WASHINGTON, PA 19034

Individual Safety Report
3149261-X-00-01

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FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
01170943	37 yrs	( )female	lbs
In confidence	or Date of birth: [redacted]	(X)male	or 78 kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

(X) death 9/29/94 (mo/day/yr)
( ) life-threatening
(X) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event	4. Date of this report
9/25/94 (mo/day/yr)	10/16/98 (mo/day/yr)

5. Describe event or problem

Notification via litigation of case summaries provided by physician/co-author of literature report (N Engl J Med 1997; 337:1112-7). Info provided based on extracted data from medical records of pts hospitalized for acetaminophen ingestion between 1/1/92 & 4/30/95. According to extracted data, a 37 yo M with hx of regular ethanol use ingested Extra Strength TYLENOL® (ACCIDENTAL OVERDOSE) over 8 hr period on 9/25/94 for toothache. Pt had NAUSEA & VOMITING & abdominal pain 2 days PTA. On 9/27/94 pt was admitted to ICU w/ diagnoses of acute liver failure (HEPATIC FAILURE) & acute renal failure (KIDNEY FAILURE). Pt expired (DEATH) on 9/29/94. Addl info rec'd 10/13/98: med records indicate pt ingested 60 Extra Strength TYLENOL according to brother. Pt had nausea, coffee-ground emesis, & abdominal pain. On hosp day 1, pt treated for COAGULATION DISORDER & (GASTROINTESTINAL HEMORRHAGE). Pt received MUCOMYST® & underwent hemodialysis. On hosp day2, pt had focal seizures (CONVULSIONS) & showed evidence of intracranial edema. Pt expired after extubation.

6. Relevant tests/laboratory data, including dates

9/26/94 WBC=25.7, AST=13290, AlkP=96, Tbili=4.4, TP=6.9, Alb=3.9, Creat=3.3, K=6.8, Cl=90, CO2=15, Alb=3.9, LD=12200; 9/27/94 acetaminophen=7, ETOH level negative, a-HBc=positive, a-HCV=positive, HBsAg=negative (See Sect B7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

hx of regular ethanol use - approx 6 pk/d, sometimes an extra 2-3 beers (last drink on 9/25/94), hx of IV drug abuse six yrs ago for 6 mos, hx of smoking 1 ppd x 20 yrs, hx of [illegible]/D & hiatal hernia (Sect B6 cont) a-HBC IgM=negative, a-HAV =negative, PT=50.2, PTT=59.1, CK=703; 9/29/94 WBC=13.5, [illegible]o=11.6, HCT=32.7, PLT=36, PT=35.5, PTT=38.5 (See Sect C10)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL product
#2

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 30 g over 8 hours, po	#1 9/25/94; 1 day
#2	#2

4. Diagnosis for use (indication)

#1 toothache
#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2	#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

penicillin VK (9/25/94)
Sect B7 cont: TP=4.9, Alb=2.8, ALT=3010, AST=3290, Tbili=9.3, GGT=138, Na=150, CO2=17, Gluc=41, Creat=5.1, urine culture-e.coli & yeast

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
( ) consumer
(X) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 10/13/98

5. IND, protocol #

6.
(A) NDA # 17-552
IND #
PLA #
pre-1838 ( ) Yes
OTC product (X) Yes

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
( ) Initial (X) follow-up # 1

8. Adverse event term(s)

OVERDOSE ACCID
NAUSEA VOMIT
LIVER FAILURE
KIDNEY FAILURE
COAGULATION DIS
HEMORRHAGE GI
CONVULSION
DEATH

9. Mfr. report number: 0903966A

E. Initial reporter

1. Name, address & phone #

[redacted] MD
[redacted] Medical Ctr
[redacted] Boulevard
[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.